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**TRANSMITTAL  
FORM**

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Total Number Of Pages In This Submission

Application Number	09/940,316	<b>RECEIVED</b> <i>SEP 11 2002</i>
Filing Date	August 27, 2001	
First Named Inventor	Christopher REEVES	
Group Art Unit	1652	
Examiner Name	To Be Assigned	TECH CENTER 1600/2900

**ENCLOSURES (check all that apply)**

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> Fee Transmittal Form                                       | <input type="checkbox"/> Assignment Papers<br>(for an Application)                      | <input type="checkbox"/> After Allowance Communication to Group                                 |
| <input type="checkbox"/> Fee Attached   | <input type="checkbox"/> Drawing(s)   | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences             |
| <input type="checkbox"/> Amendment / Reply  | <input type="checkbox"/> Licensing-related Papers                                       | <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)      |
| <input type="checkbox"/> After Final  | <input type="checkbox"/> Petition   | <input type="checkbox"/> Proprietary Information  |
| <input type="checkbox"/> Affidavits/declarations                                    | <input type="checkbox"/> Petition to Convert to a Provisional Application               | <input type="checkbox"/> Status Letter  |
| <input type="checkbox"/> Extension of Time Request                                  | <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Return postcard |
| <input type="checkbox"/> Express Abandonment Request                                | <input type="checkbox"/> Terminal Disclaimer  |   |
| <input checked="" type="checkbox"/> Information Disclosure Statement; PTO form 1449 | <input type="checkbox"/> Request for Refund   |   |
| <input type="checkbox"/> Certified Copy of Priority Document(s)                     | <input type="checkbox"/> CD, Number of CD(s) _____                                      |   |
| <input type="checkbox"/> Response to Missing Parts/ Incomplete Application          |   |   |
| <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53        |   |   |

Remarks

**SIGNATURE OF APPLICANT, ATTORNEY OR AGENT**

Firm or Individual Name	Brenda J. Wallach Registration No. 45,193
Signature	
Date	August 30, 2002

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on August 30, 2002.

Garee A. Haney

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PATENT  
Docket No. 300622002611

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE TECH CENTER 1600/2900

In the application of:

Christopher REEVES et al.

Serial No.: 09/940,316

Filing Date: August 27, 2001

For: POLYNUCLEOTIDES ENCODING THE  
*fkbA* GENE OF THE FK-520  
POLYKETIDE SYNTHASE GENE  
CLUSTER

Examiner: To Be Assigned

Group Art Unit: 1652

**SUPPLEMENTAL INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents were previously submitted in an Information Disclosure Statement and/or Office Action, directed to the related application Serial Number 09/410,551, filed October 1, 1999, and, accordingly, copies are not included herewith. This protocol conforms with 37 C.F.R. § 1.98(d) and M.P.E.P. 609(A)(2). The Examiner is requested to make these documents of record in the application. The Examiner is requested to make these documents of record.

This application is a Divisional of United States Serial Number 09/410,551, filed October 1, 1999, which claims the benefit of the filing date of United States Provisional Application Serial Numbers 60/102,748, filed October 2, 1998; 60/139,650, filed June 17, 1999; and 60/123,810, filed March 11, 1999.

This Information Disclosure Statement is submitted:

- Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - A fee is required. A check in the amount of \* is enclosed.
  - A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of \* is enclosed.
  - A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Supplemental Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 300622002611. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 30, 2002

Respectfully submitted,

By. Brenda J. Wallach  
Brenda J. Wallach  
Registration No. 45,193

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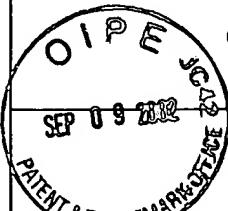
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Sheet 1 of 2

Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 300622002611	Application Number 09/940,316
Applicant	Christopher REEVES et al.
Filing Date August 27, 2001	Group Art Unit 1652
Mailing Date August 30, 2002	



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## U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	02/1993	5,189,042	Goulet et al.	514	291	
	2.	09/1997	5,672,491	Khosla et al.	435	148	
	3.	01/1998	5,712,146	Khosla et al.	435	252.35	
	4.	10/1999	5,968,921	Gold	514	183	
	5.	11/2000	6,150,513	Wu	536	23.2	
	6.	04/2001	6,210,974	Gold	436	501	

## FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	7.	07/05/1989	EP 0323042A	EPO			
	8.	02/28/1990	EP 0356399A	EPO			
	9.	01/02/1992	EP 0463690A	EPO			

## OTHER DOCUMENTS

(including author, title, Date, Pertinent Pages, Etc.)

Examiner Initials	Ref. No.	Title
	10.	Chen T.S. et al. (1992). "Microbial Transformation of Immunosuppressive Compounds. II. Specific desmethylation of 13-methoxy group of FK 506 and FR 9500520 by Actinomycete sp. ATCC 53828," <i>J Antibiot</i> 45(4):577-580.
	11.	Dumont F.J. et al. (1992). "The Immunosuppressive and Toxic Effects of FK-506 Are Mechanically Related: Pharmacology of a Novel Antagonist of FK-506 and Rapamycin," <i>J of Exp Medicine</i> 176(3):751-760.
	12.	Gold et al., (1995) <i>Journal of Neuroscience</i> 15:7509-7516
	13.	Gold et al., (1999) <i>J. Pharm. Exp. Ther.</i> 289(3):1202-1210
	14.	Harrison's Principles of Internal Medicine, 14th Edition, 1998, McGraw Hill, Chapters 14,20,21,64-67
	15.	Iwasaki et al., (1993) <i>Drug Metabolism and Disposition</i> 21:971-977
	16.	Iwasaki et al., (1995) <i>Drug Metabolism and Disposition</i> 23:28-34

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Form PTO-1449

INFORMATION DISCLOSURE CITATION  
IN AN APPLICATION

(Use several sheets if necessary)

Docket Number 300622002611

Application Number 09/940,316

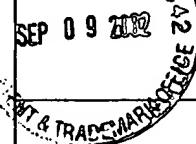
Applicant

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Filing Date August 27, 2001

Group Art Unit 1652

Mailing Date August 30, 2002



17.	Kawai et al., (1993) FEBS Letters 316(2):107-113	RECEIVED SEP 11 2002 TECH CENTER 1600/2900
18.	Khosla C. (1997). "Harnessing the Biosynthetic Potential of Modular Polyketide Synthases," <i>Chemical Reviews</i> 97(7):2577-2590.	
19.	Lyons et al., (1994) Proc. Natl. Acad. Sci. USA 91:3191-3195	
20.	Motamedi et al., (1996) J. Bacteriol. 178:5243-5248	
21.	Motamedi et al., (1997) Eur. J. Biochem. 244:78-80	
22.	Motamedi and Shafiee, (1998) Eur. J. Biochem. 256:528	
23.	Reynolds K.A. et al. (1997). "Rapamycin, FK506, and Ascomycin-related Compounds," <i>Drugs Pharm Sci</i> 82:497-520.	
24.	Shafiee A. et al. (1993). "Enzymatic synthesis and Immunosuppressive Activity of Novel Desmethylated Immunomycins (Ascomycins)," <i>J Antibiot</i> 46(9):1397-1405.	
25.	Shiraga et al., (1994) Biochem. Pharmacol. 47:727-735	
26.	Stassi D.L. et al. (1998). "Ethyl-substituted Erythromycin Derivatives Produced by Directed Metabolic Engineering," <i>Proc Natl Acad Sci USA</i> 95 (13):7305-7309.	
27.	Steiner et al., (1997) Proc. Natl. Acad. Sci. USA 94:2019-2024	
28.	Vincent et al., (1992) Arch. Biochem. Biophys. 294:454-460	
29.	Wu et al., (2000) Gene 251:81-90	

EXAMINER:

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